## INFORMATION DISCLOSURE STATEMENT BY APPLICANT OCT 1 6 2007 (use as many sheets as necessary)

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Sheet 1

of 2

Complete if Known

Application Number 09/525,797

Filing Date March 15, 2000

First Named Inventor Athanasius A. Anagnostou

Group Art Unit 1642

Examiner Name Susan Ungar

Attorney Docket Number 5218-39B

| U.S. PATENTS AND PATENT PUBLICATIONS |          |                                       |                         |  |                              |  |  |
|--------------------------------------|----------|---------------------------------------|-------------------------|--|------------------------------|--|--|
| Examiner<br>Initials*                | Cite No. | U.S. Patent Document                  |                         | Name of Patentee or Applicant of Cited | Date of Publication of Cited |  |  |
|                                      |          | Number                                | Kind Code<br>(if known) | Document                               | Document<br>MM-DD-YYYY       |  |  |
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| U.S. PATENT APPLICATIONS |          |                 |                                     |   |  |
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| Examiner<br>Initials*    | Cite No. | U.S. Serial No. | Name of Applicant of Cited Document | Date of Filing of Cited Document MM-DD-YYYY |  |
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| FOREIGN PATENT DOCUMENTS |             |                         |        |                         |  |   |             |
|--------------------------|-------------|-------------------------|--------|-------------------------|--|---|-------------|
| Examiner<br>Initials*    | Cite<br>No. | Foreign Patent Document |        | cument                  | Name of Patentee or Applicant of Cited | Date of   | Translation |
|                          |             | Office                  | Number | Kind Code<br>(if known) | Document                               | Publication of<br>Cited<br>Document<br>MM-DD-YYYY |             |
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|   |                     | OTHER NON PATENT LITERATURE DOCUMENTS  |                |
|---|---------------------|--|----------------|
| Examiner Initials*                      | Cite<br>No.         | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T              |
|   | 1.                  | English translation of "Notice of Opposition" filed by Bioceuticals Arzneimittel AG 1-6 (2005) including the following D1-D9 annexed documents   |                |
|   | D1                  | WO 98/10650 to East Carolina University 03/19/1998 including International Search Report dated 10/24/1997  |                |
|   | D2                  | Rubins et al. "Metastatic Renal Cell Carcinoma" Annals of Internal Medicine 122(9):676-677 (1995)  |                |
|   | D3                  | Carlini et al. "Recombinant human erythropoietin stimulates angiogenesis in vitro Kidney International 47:740-745 (1995)   |                |
|   | D4                  | Höckel et al. "Therapeutic Angiogenesis" Arch Surg 128:423-429 (1993)  |                |
|   | D5                  | Sungur, Cem "Renal Cell Carcinoma and Erythropoietin" <i>Annals of Internal Medicine</i> <b>123</b> (9):732-733 (1995)   |                |
|   | D6                  | Anagnostou et al. "Erythropoietin has a mitogenic and positive chemotactic effect on endothelial cells" <i>Proc. Natl. Acad. Sci.</i> <b>87</b> :5978-5982 (1990)  |                |
|   | D7                  | Carlini et al. "Recombinant human erythropoietin (rHuEPO) increases endothelin-1 release by endothelial cells" <i>Kidney International</i> <b>43</b> :1010-1014 (1993)   |                |
|   | D8                  | Nagai et al. "Effects of rHuEpo on cellular proliferation and endothelin-1 production in cultured endothelial cells" <i>Nephrol Dial Transplant</i> <b>10</b> :1814-1819 (1995)  |                |
|   | D9                  | Yamaji et al. "Brain capillary endothelial cells express two forms of erythropoietin receptor mRNA" <i>Eur. J. Biochem</i> <b>239</b> :494-500 (1996)  |                |
|   | D10                 | Miller et al. "Phase I-II Trial of Erythropoietin in the Treatment of Cisplatin-Associated Anemia" J Natl Cancer Inst 84(2): 98-103 (1992)   |                |
|   | 2.                  | English translation of "Observations of Patentee in Reply" 22 pages (2006) including the following A1-A8 annexed documents   |                |
| 200000000000000000000000000000000000000 | <del>Д</del> ифинин | English translation of the Opposition Otatement  | 10000000000000 |
| 000000000000000000000000000000000000000 | <del></del>         | Timeline of treatments given to patient of D1 (1 page)   | ю ососоо       |
|   | А3                  | Prescribing information for Procrit® (1-36) (2005)   |                |
|   | A4                  | BCCA Protocol Summary for Alpha-interferon (α-IFN) for Advanced Renal Cell Carcinoma (2006)  |                |
|   | A5                  | Neidhart, J.A. "Interferon therapy for treatment of renal cancer" <i>Cancer</i> <b>57</b> (8 Suppl):1696-1699 (1986) ABSTRACT  |                |

| Examiner Signature | /Karen A. Canella, Ph.D./ | Date Considered | 08/18/2008 |
|--------------------|---------------------------|-----------------|------------|
|                    |                           |                 |            |

|                                   | C                      | Complete if Known        |  |  |
|-----------------------------------|------------------------|--------------------------|--|--|
|                                   | Application Number     | 09/525,797               |  |  |
| INFORMATION DISCLOSURE            | Filing Date            | March 15, 2000           |  |  |
| STATEMENT BY APPLICANT            | First Named Inventor   | Athanasius A. Anagnostou |  |  |
| OTATEMENT BY ALL ELONG            | Group Art Unit         | 1642                     |  |  |
| (use as many sheets as necessary) | Examiner Name          | Susan Ungar              |  |  |
| Sheet 2 of 2                      | Attorney Docket Number | 5218-39B                 |  |  |

| F                     | 1 0:4-      | OTHER NON PATENT LITERATURE DOCUMENTS  Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal,  | T                                       |
|-----------------------|-------------|---|---|
| Examiner<br>Initials* | Cite<br>No. | serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published  | T                                       |
|                       | A6          | Whiteway et al. "An extremely delayed cytogenetic response to interferonalpha in a patient with chronic myeloidleukaemia" <i>Leukemia</i> 11(4):614-616 (1997)  |   |
|                       | A7          | <a href="http://www.cancerguide.org/rcc_metastatic.html">http://www.cancerguide.org/rcc_metastatic.html</a> >1-4 (2006)   |   |
|                       | A8          | <a href="http://www.noetic.org/research/sr/faqs/html">http://www.noetic.org/research/sr/faqs/html</a> 1-4 (2006)  |   |
|                       | 3.          | English translation of "Response to the Patentee's Observations of 27 <sup>th</sup> April2006" 1-17 (2006) including the following D11-D13 annexed documents  |   |
|                       | D11         | Shinkelgaku et al. "Multiple cerebral infarction after treatment with cisplatin" Rinsho Shinkeigaku 36(3):499-502 (1996) ABSTRACT   |   |
|                       | D12         | Ito et al. "Vitamin E prevents endothelial injury associated with cisplatin injection into the superior mesenteric artery of rats" <i>Heart Vessels</i> <b>10</b> (4):178-184 (1995) ABSTRACT                           |   |
|                       | D13         | Breymann et al. "Optimal timing of repeated rh-erythropoietin administration improves its effectiveness in stimulating erythropoiesis in healthy volunteers" <i>Br J Haematol</i> <b>92</b> (2):295-301 (1996) ABSTRACT |   |
|                       | 4.          | English translation of "Opponent's Rule 71A EPC Submissions File" 1-40 2007   |   |
|                       | 5.          | English translation of "Patentee's Rule 71(a) EPC Submissions 29 pages (2007)   |   |
|                       |             | including the following A9-A13 annexed documents  | <u> </u>                                |
|                       |             | English translation of the Opposition statement 1-17  | 000000000                               |
|                       | A10         | Expert Witness Statement of Professor Alexander F. Markham including his Curriculum Vitae 1-51 (2006)   |   |
|                       | A11         | Freed et al. "Idiopathic Regression of Metastases from Renal Cell Carcinoma" <i>The Journal of Urology</i> <b>118</b> :538-542 (1977)   |   |
|                       | <del></del> | In vivo further experimental data from the Patentee (cisplatin and tumour weight and volume)  | *************************************** |
|                       | A13         | In vivo further experimental data from the Patentee (bleomycin and functional changes of the  | 00000000000                             |
|                       |             | epithelium) (2 pages)   |   |

| Examiner Signature | /Karen A. Canella, Ph.D./ | Date Considered | 08/18/2008 |   |
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